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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,180	08/05/2002	Alistair Dixon	A0000096-01-SMH	2579

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EXAMINER	
HUI, SAN MING R	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 02/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/031,180	DIXON ET AL.	
	Examiner	Art Unit	
	San-ming Hui	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-53* is/are pending in the application.

4a) Of the above claim(s) *26-51* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25,52 and 53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1-16-02, 2-25-03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of the invention of Group I, claims 1-25 and 52-53, and the specie, N-cyclopropylmethoxy-3,4,5-trifluoro-2-(4-iodo-2-methyl-phenylamino)-benzmaide in response filed October 7, 2004 is acknowledged. The traversal is on the ground(s) that a single general inventive concept exists. This is not found persuasive because the single inventive concept has to be makes contribution over the prior arts. In the instant case, the various compounds listed in the different groups of invention as set forth in the previous office action are known (See WO99/01421 and WO99/01426 from IDS received January 16, 2002). Therefore, no special technical features are seen to be present herein.

The requirement is still deemed proper and is therefore made FINAL.

Claims 26-51 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on October 7, 2004.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The limitation ""any other nerve injury between ... central nervous system" recited in claim 4 renders the claim indefinite. It is unclear what other nerve injury would be encompassed by the claim and therefore the pain that is treatable by the herein claimed compounds would not be defined.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4, 9-25 and 52-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO99/01426 ('426).

'426 teaches the elected specie ***N-cyclopropylmethoxy-3,4,5-trifluoro-2-(4-iodo-2-methyl-phenylamino)-benzmaide*** as MEK inhibitors that is useful in treating proliferative diseases such as cancer (See page Compound example 79, also the abstract).

'426 does not expressly teach the elected specie as useful in treating chronic pain.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the elected specie in a method of treating chronic pain.

One of ordinary skill in the art would have been motivated to employ the elected specie in a method of treating chronic pain since cancer is always associated with chronic pain. Therefore, employing the elected specie in a method of treating cancer in cancer patients before or after surgical removal of the cancer and thereby providing chronic pain relief would be reasonably expected to be effective.

Furthermore, neuroma is a brain tumor that affecting the auditory nerve in the head. Therefore, the method of employing the elected specie to treat such tumor (proliferative disease) would be reasonably expected to be useful.

Claims 1-4, 6-25 and 52-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO99/01421 ('421).

'421 teaches a 4-iodo phenylamino benzamide compounds, including the elected specie, as MEK inhibitors and as useful to treat diabetes, proliferative disorders such as cancer, and inflammation (See the abstract, claims 26, 31, 33).

'426 does not expressly teach the elected specie as useful in treating chronic pain.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the elected specie in a method of treating chronic pain.

One of ordinary skill in the art would have been motivated to employ the elected specie in a method of treating chronic pain since cancer is always associated with

chronic pain. Therefore, employing the elected specie in a method of treating cancer in cancer patients before or after surgical removal of the cancer and thereby providing chronic pain relief would be reasonably expected to be effective.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over '426 or '421 as applied to claims 1-4, 6-25, and 52-53 above, and further in view of Ru-Hong et al. (Nature neuroscience, 1999;2(12):1114 -1119 from IDS received January 16, 2002).

'421 and '426 suggest that the elected specie as useful as MEK inhibitors and as a treatment for chronic pain.

Neither '421 or '426 teach the elected specie as useful in treating chronic pain associated with the disorders recited in claim 5.

Ru-Hong et al. teaches MEK inhibitors as useful in blocking pain-related behavior which may be because of the MEK blocking capabilities that reduce the ERK activation (See page 1116, col. 2 – page 117, col. 2, Discussion Section).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the elected specie MEK inhibitor in the method of treating chronic pain associated with the disorders recited in claim 5.

One of ordinary skill in the art would have been motivated to employ the elected specie MEK inhibitor in the method of treating chronic pain associated with the disorders recited in claim 5. Since MEK inhibitor as useful in blocking pain-related behavior, employing any known MEK inhibitors such as the elected specie, would be reasonably expected to be effective.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (571) 272-0626. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

San-ming Hui
Primary Examiner
Art Unit 1617